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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,840	07/06/2001	Mark Leslie Smythe	36677.8	8048
27683 7590 08/08/2008 HAYNES AND BOONE, LLP 901 Main Street Suite 3100 Dallas, TX 75202				
EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
08/08/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/787,840

Applicant(s)

SMYTHE ET AL.

Examiner

CHIH-MIN KAM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-31, 35 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-16, 35, 41 and 42 is/are allowed.
- 6) ☒ Claim(s) 43 is/are rejected.
- 7) ☒ Claim(s) 17-31, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Page No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

1. Claims 1-5, 7-31, 35 and 39-43 are pending.

Applicant's amendment filed May 5, 2008 is acknowledged, and applicants' response has been fully considered. Claims 1, 14, 23 and 41-43 have been amended. Therefore, claims 1-5, 7-31, 35 and 39-43 are examined.

Withdrawn Claim Objections

2. The previous objection to claim 11 is withdrawn in view of applicants' amendment of the claims, and applicant's response at page 23 in the amendment filed May 5, 2008.

Withdrawn Claim Rejections - 35 U.S.C. § 112

3. The previous rejection of claims 1-5, 7-10, 12-31, 35 and 39-43 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicants' amendment of the claims, and applicant's response at page 22 in the amendment filed May 5, 2008.

Claim Objections

4. Claims 17-31, 39 and 40 are objected to because the claims recites "linking an auxiliary compound as defined in claim 1", while claim 1 and claims 17-31, 39 and 40 are all method claims. It is more appropriate to change claims 17, 22, 24, 26 and 30 to independent form that recites the auxiliary compound of General Formula II having all the definitions for each functional group in the formula II as shown in claim 1.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 is directed to a method of on-resin cyclization of a peptide or peptidomimetic, comprising at least the steps of using a cyclic aromatic auxiliary compound of the formula $C_6H_3(CHO)(OH)(NO_2)$ as a linker linking the alpha-nitrogen of an amino acid residue in the desired peptide or peptidomimetic to a solid support to form a secondary amine; synthesizing a linear peptide or peptidomimetic on a solid support, using standard solid phase peptide synthesis methods; deprotecting the desired amine and carboxylic acid groups; activating the carboxylic acid group to perform cyclization and optionally deprotecting amino acid side chain groups; and/or cleaving the cyclic peptide from the solid support.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional

characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses using the auxiliary compound of the General Formula II having a covalent linkage to a solid support and the linear peptide can be cyclized on-resin (page 24, line 6 to page 26, line 26), the specification does not disclose using the compound of the formula $C_6H_5(CHO)(OH)(NO_2)$ as a linker linking the alpha-nitrogen of an amino acid residue in the peptide or peptidomimetic to a solid support, and synthesizing a peptidomimetic on a solid support, using standard solid phase peptide synthesis methods. The disclosure of using the compound of the General Formula II as an auxiliary compound to facilitate on-resin cyclization of a peptide in the claimed method does not provide sufficient written description for using the compound of the formula $C_6H_5(CHO)(OH)(NO_2)$ as an auxiliary compound to facilitate on-resin cyclization of a peptide or a peptidomimetic since there is no functional group in the compound of $C_6H_5(CHO)(OH)(NO_2)$ linked to a solid support. Furthermore, the specification does not disclose a peptidomimetic can be synthesized on a solid support using standard solid phase peptide synthesis methods. Without guidance on the method steps of using the compound of the formula $C_6H_5(CHO)(OH)(NO_2)$ as an auxiliary compound to facilitate on-resin cyclization of a peptide or a peptidomimetic, one skilled in the art would not know how the compound of $C_6H_5(CHO)(OH)(NO_2)$ is used as an auxiliary compound in the claimed method. The lack of

description of using the compound of $C_6H_5(CHO)(OH)(NO_2)$ as an auxiliary compound to facilitate on-resin cyclization of a peptide or a peptidomimetic, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite because of the use of term “using a cyclic aromatic auxiliary compound of the formula $C_6H_5(CHO)(OH)(NO_2)$ as a linker linking the α -nitrogen of an amino acid residue in the desired peptide of peptidomimetic to a solid support.....” or “(ii) synthesizing a linear peptide or peptidomimetic on a solid support, using standard solid phase peptide synthesis methods”. The term cited renders the claim indefinite, it is not clear how the compound of the formula $C_6H_5(CHO)(OH)(NO_2)$ is used as a linker to link to a solid support since the compound does not have a functional group to link to a solid support; and it is also not clear how a peptidomimetic is synthesized by a standard solid phase peptide synthesis method since the peptidomimetic is not a peptide. It is noted that the citation should be linking alpha-nitrogen of an amino acid residue in the desired peptide or peptidomimetic to a solid support, not “ α -nitrogen” and “of peptidomimetic” in the claim.

Conclusion

7. Claim 43 is rejected; and claims 17-31, 39 and 40 are objected to. It appears that claims 1-5, 7-16, 35, 41 and 42 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

August 5, 2008